

COP 08#22

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PTO/SB/21 (PS-10)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. 09/464,416 **Application Number** TRANSMITTAL **Filing Date December 16, 1999 FORM** Yasmin Thanavala First Named Inventor 1651 Group Art Unit (to be used for all correspondence after initial filing) M. Flood **Examiner Name** RPP:156B US Attorney Docket Number Total Number of Pages in This Submission

		ENGLOCUPED (
ENCLOSURES (check all that apply)									
Fee Transmittal Form		Assignment Papers (for an Application)	After Allowance Communication to Group						
Fee Attached Amendment / Reply After Final Affidavits/declaration(s) Extension of Time Request Express Abandonment Request Information Disclosure Statement Certified Copy of Priority Document(s) Response to Missing Parts/ Incomplete Application		Drawing(s) Licensing-related Papers Petition Petition to Convert to a Provisional Application Power of Attorney, Revocation Change of Correspondence Address Terminal Disclaimer Request for Refund CD, Number of CD(s) Remarks	Appeal Communication to Board of Appeals and Interferences Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) Proprietary Information Status Letter Other Enclosure(s) (please identify below):						
Response to Mis under 37 CFR 1	- 1		901590 57						
	SIGNATU	RE OF APPLICANT, ATTORNEY, O	R AGENT						
or Individual name Dunr	ael L. Dunn & Associa Induc	tes							
Date How. 5, zwo (
CERTIFICATE OF MAILING									
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Typed or printed name Michael L. Dunn									
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O PEE TRANSMITTAL		Application Number 09/		09/464,416	
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JAN 2 2 2002 For FY 2001				Yasmin Thanavala	20,
Patent lees are subject to annual revision.	Examiner Na			M. Flood	
TOTAL AMOUNT OF PAYMENT (\$)	Group Art U Attorney Do			1651 7/60 RPP:156B US	2/2/2
METHOD OF PAYMENT	Attorney Do			ALCULATION (continued)	2000
The Commissioner is hereby authorized to charge	3. ADDIT				
indicated fees and credit any overpayment to:	Large	e	Smail		
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Deposit	105 130	205	65	Surcharge - late filing fee or oath	
Account Name	127 50	227	25	Surcharge - late provisional filing fee or cover sheet	
Charge Any Additional Fee Required	139 130	139	130	Non-English specification	
Under 37 CFR 1.16, 1.17, 1.18 and 1.20	147 2,520	147	2,520	For filing a request for ex parte reexamination	
Applicant claims small entity status. See 37 CFR 1.27	112 920*	112	920*	Requesting publication of SIR prior to Examiner action	
2. Check Credit Card Money Order Other	113 1,840*	113	1,840*	Requesting publication of SIR after Examination action	
FEE CALCULATION	115 110	215	55	Extension for reply within first month	
1. BASIC FILING FEE	116 390	216	195	Extension for reply within second month	$\parallel \parallel \parallel$
Large Entity Small Entity Fee Fee Fee Fee Description	117 890	217	445	Extension for reply within third month	<u> </u>
Code (\$) Code (\$) Fee Paid	118 1,390	218	695	Extension for reply within fourth month	
101 710 201 355 Utility filing fee	128 1,890	228	945	Extension for reply within fifth month	
106 320 206 160 Design filing fee	119 310	219	155	Notice of Appeal	
107 490 207 245 Plant filing fee	120 310	220	155	Filing a brief in support of an appeal	
108 710 208 355 Reissue filing fee	121 270	221	135	Request for oral hearing	
114 150 214 75 Provisional filing fee	138 1,510	138	1,510	Petition to institute a public use proceeding	
	140 110	240	55	Petition to revive - unavoidable	
SUBTOTAL (1) (\$)	141 1,240	241	620	Petition to revive - unintentional	-
2. EXTRA CLAIM FEES	142 1,240	242	620	Utility issue fee (or reissue)	
Fee from	143 440	243	220	Design issue fee	
Extra Claims below Fee Paid		244	300	Plant issue fee	<u> </u>
Total Claims -20** = X =		122	130	Petitions to the Commissioner	$\vdash \vdash \vdash \vdash \vdash$
Independent -3** = X = -		122		Processing fee under 37 CFR 1.17(q)	$\sqcup \sqcup \sqcup$
Claims			50	•	
Multiple Dependent	126 180	126	180	Submission of Information Disclosure Stmt	
Large Entity Small Entity	581 40	581	40	Recording each patent assignment per property (times number of properties)	
Fee Fee Fee Fee Fee Fee Description Code (\$) Code (\$) 103 18 203 9 Claims in excess of 20	146 710	246	355	Filing a submission after final rejection (37 CFR § 1.129(a))	
102 80 202 40 Independent claims in excess of 3	149 710	249	355	For each additional invention to be examined (37 CFR § 1.129(b))	
104 270 204 135 Multiple dependent claim, if not paid	179 710	279	355	Request for Continued Examination (RCE)	
109 80 209 40 **Reissue independent claims over original patent	169 900	169	900	Request for expedited examination	
110 18 210 9 **Reissue claims in excess of 20 and over original patent	Other fee (sp	ecify)		of a design application	
SUBTOTAL (2)	*Reduced by E	Basic Fil	ing Fee	Paid SUBTOTAL (3) (S)	
**or number previously paid, if greater, For Reissues, see above					
SUBMITTED BY				Complete (if applicable)	
Name (Print/Type) Michael L. Dunn Registration No. (Attorney/Agent)	25,330			Telephone 716-433-1661	
Signature Machaello				Date 11/05/0	,

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RPP:1568 US TO THE BOARD OF PATENT APPEALS AND INTERFERENCES IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Yasmin Thanavala, et al.

Art Unit:

1651

Serial No:

09/464,416

Filed:

December 16, 1999

I certify that this **Reply Brief** is being deposited on **November 5, 2001** with the U.S. Postal Service as first class

Examiner:

M. Flood

mail addressed to the Assistant Commissioner for Patents,

Washington, D.C. 20231

For:

ORAL IMMUNOLOGY USING

PLANT PRODUCT CONTAINING

CONTAINING A NON- ENTERIC

PATHOGEN ANTIGEN

Michael L. Dunn

Registration No. 25,330

REPLY BRIEF

Box AF Assistant Commissioner for Patents Washington, DC 20231

Sir:



The attorney for the Appellants considers that most arguments showing patentability of the claims have already been set forth in the Appeal Brief.

We do, however, wish to point out the Examiner's rejections are inconsistent on their face.

In attempting to support the art rejection under 35 USC 103, the Examiner on page 10 of the Answer says:

"Thus, one would have had a reasonable expectation of success to provide a therapeutic regimen such as the one in the claimed invention because the determination of an effective treatment method for providing an immune response by the oral ingestion of the claim-designated drug in combination with an orally effective adjuvant in an individual which was greater than the response elicited by the NEPA alone would have been a matter of routine optimization to one of ordinary skill in the art at the time the invention was made."

This statement (admission) is made by the Examiner based upon the Examiner's view of

the cited art alone without consideration of the teachings in the current specification which is the

only true teaching and suggestion of "a method for providing a specific immune response by

feeding a mammal with genetically altered potato expressing a NEPA with an adjuvant", (see

Examiner's Answer page 8, lines 13-16).

The Examiner's statement on page 10 of the Examiner's Answer is completely

inconsistent with the statement by the Examiner on page 5 used to support the Examiner's 35

USC 112 rejection, i.e., "However, the specification does not provide sufficient guidance as to

how one of ordinary skill in the art would provide an immune response in a mammal and/or a

human to a NEPA other than the non-enteric pathogen antigen, hepatitis B surface antigen."

The Examiner's Answer thus says on page 10 that the state of the art alone is sufficient to

reduce the claimed invention to practice as "a matter of routine optimization", but the added

detail and specific teachings of the specification to the known state of the art somehow "does not

provide sufficient guidance". The inconsistency is clear.

Both the 35 USC 112 and 35 USC 103 rejections should be reversed and the claims

should be allowed.

Dated: November 5, 2001

Respectfully submitted,

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